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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/507,345

03/24/2005

Ubaldo Conte

28069-603 NATL

3809

35437

7590

04/16/2009

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EXAMINER

AZPURU, CARLOS A

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

04/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/507,345	Applicant(s) CONTE ET AL.	
	Examiner Carlos A. Azpuru	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the response and information disclosure statement filed 01/29/2009.

While the references were provided, an accompanying PTOL-1449 was not provided. Applicant is requested to provide this for next action so that the references can be made of record and considered appropriately.

The following rejections are maintained in this action:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Conte (US Patent No. 5487901).

Conte discloses a pharmaceutical tablet composed of an upper layer containing active ingredient formulated for immediate release, and lower layer of the same formulation as the upper layer containing identical or different active agents and being

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almost completely coated with an insoluble polymeric coating (col 2, lines 30-45). The tablet is completely coated with an impermeable film (col. 2, lines 52-53). The upper layer also comprises polymeric excipients (col. 4, lines 1-9). The amount of the excipient with respect to the total weight of the tablet is 1-90% by wt (col. 4, lines 10-13). The upper layer is 0.5 -5 mm thick. (col. 4, line 39). The amount of polymeric substance in respect to the total weight of the tablet is 5-90% (col. 4, line 55). The bottom layer is the same composition as the upper layer (col. 5, lines 32-36). The lower layer is 0.5 – 5mm thick (col. 5, line 37). The tablet is coated with an impermeable polymeric material that is insoluble or exhibits delayed solubility, or has a solubility that is pH dependent (col.5, lines 40-46). The polymeric coating with respect to the finished tablet is 0.2-20% by wt (col. 5, lines 54-55). The upper layer is partially exposed to the environmental fluid because a raised portion was removed after the final coating step with impermeable polymeric coating (col. 2, lines 54-55). The Conte reference discloses that the removal of the raised portion may be carried out by techniques already available on the market (col. 5, lines 61-64). Applicant is setting out a product by process step. As such, the process by which the product is made will only hold patentable weight if the process imparts functional or structural limitations to the product that would distinguish it from the product set out by the prior art. In the case, the prior art clearly anticipated, and the process limitation of using a laser to incise the impermeable polymeric membrane in the product claims does not impart patentable weight. It is applicant's burden to show that the instant product is distinct from the one disclosed by Conte.

Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Conte (US Patent No. 5650169).

Conte '169 is a divisional of Conte '301 and has an identical disclosure covering all the limitations set out in the previous rejection. The instant claims are therefore anticipated by Conte'169.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Faour (US Patent No 6599284).

The applied reference has a common Faour with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

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Faour discloses a controlled release osmotic device comprised of an outer layer or external coating containing active ingredient (2), and an inner layer or core containing active ingredient ((4) and Figure 4). The dosage form also has a passageway (5) formed by a laser incision (col. 13, lines 48-55), which is incised in both the top and bottom layers (Figure 4). The addition of osmopolymers is taught at col. 16, lines 1-45, and disintegrating agents at col. 18., lines 25-38. The reference further discloses that the outer and inner layer may contain the same or different active excipients (col. 13, lines 5-7). Example 1 discloses the use of 5% by wt of polyethylene glycol (col. 24, lines 25-30). Theeuwes et al (US 4088864 discloses a CO2 laser source with an output of 20 W. Therefore both the composition and process claims are anticipated by Faour.

Response to Amendment

The declaration under 37 CFR 1.132 filed 0 is insufficient to overcome the rejection of claims 1-17 based upon 102 (b) based on US Patent Nos. 5487901 and 5650169 as set forth in the last Office action because: Although the declaration shows a difference in release profile, that limitation is not found in the claims.

Response to Arguments

Applicant's arguments filed 01/29/2009 have been fully considered but they are not persuasive.

Applicant arguments are identical in responding to the rejections of the instant claims over the three 102 rejections of record. In all instances, applicant argues that the instant formulation shows an unexpected constant steady state release and the instant formulation causes structural changes over the prior art. However, neither of these limitations are found in the claims. Applicant is arguing a limitation not found in the instant invention. As such, the rejections under 35 USC 102(b) over US Patent Nos. 5,487,901 and 5,650,169 as well as 35 USC 102(e) over Faour are maintained.

It is suggested that applicant amend the claims to refer to these limitations and site support from the original specification for each.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos A. Azpuru/
Primary Examiner, Art Unit 1615

Carlos A. Azpuru
Primary Examiner
Art Unit 1615

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